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Spinal Surgery  
Scoliosis and Spinal Deformities  
General Orthopaedic Surgery

December 2, 1999

Food and Drug Administration  
Attention: Document Branch HFA-305  
5630 Fishers Lane, Room 1061  
Rockville, M.D. 20852

Reference#: 97N-484S

Dear FDA Regulatory Personnel:

As a practicing orthopaedic spinal surgeon, I would like to voice my concerns about changing the regulation of Allograft human tissue into a new category.

I understand use of Allograft bone products has some overlap with that used the metallic devices and other surgical implants. I think it would be unwise to modify the existing regulations of Allograft tissue. The current quality and availability of bone-back tissue is excellent in so far as disease transmission and graft tracking. I think that additional regulation to these products would be unwise at this time.

Thank you for your time and consideration.

Sincerely,

Kevin Jon Lawson, M.D.

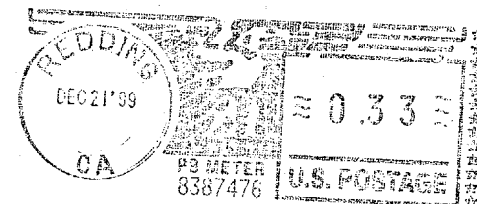
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Diplomate American Board of Orthopaedic Surgery  
Fellow American Academy of Orthopaedic Surgery

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